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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/536,750 09/29/95 DRIZEN 22890

EXAMINER

HULINA, A

15M2/0703

NATH AND ASSOCIATES

1835 K STREET NW

SUITE 750

WASHINGTON DC 20006

ART UNIT

PAPER NUMBER

DATE MAILED: 1501

07/03/96

This is a communication from the examiner in charge of your application.

COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☐ Responsive to communication(s) filed on _____
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-51 is/are pending in the application.
- Of the above, claim(s) 15-51 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-14 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claims 1-51 are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Serial Number: 08/536,750
Art Unit: 1501

-2-

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-14, drawn to a drug composition, classified in Class 424, subclass 400

Group II. Claims 15-21, drawn to a gelled composition, classified in Class 514, subclass 944.

Group III. Claims 22-34, drawn to a method of treatment, classified in Class 424, subclass 422.

Group IV. Claims 35-51, drawn to a method of making a drug composition, classified in Class 424, subclass 484.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are disclosed as different combinations which are not connected in design, operation or effect. These combinations are independent if it can be shown that (1) they are not disclosed as capable of use together, (2) they have different modes of operation, (3) they have different functions, or (4) they have different effects. (MPEP 806.04, MPEP 808.01). In the instant case the combinations they have different modes of operation.

3. Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a

Serial Number: 08/536,750
Art Unit: 1501

-3-

materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the process for using the product as claimed can be used with another materially different product such as the product of claims 15-21.

4. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as the product of claims 1-14.

5. Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different products such as that recited in claims 15-21.

6. Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2)

Serial Number: 08/536,750
Art Unit: 1501

-4-

that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)). In the instant case the process as claimed can be used to make other and materially different products such as that recited in claim 1-14.

7. Inventions III and IV are disclosed as different combinations which are not connected in design, operation or effect. These combinations are independent if it can be shown that (1) they are not disclosed as capable of use together, (2) they have different modes of operation, (3) they have different functions, or (4) they have different effects. (MPEP 806.04, MPEP 808.01). In the instant case the combinations have different modes of operation.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

9. During a telephone conversation with Gary Nath on 6-17-96 a provisional election was made with traverse to prosecute the invention of I, claims 1-14. Affirmation of this election must be made by applicant in responding to this Office action.

Claims 15-51 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in

compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

✓ 11. Claims 13 and 14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

What are the weight percents based on ?

✓ 12. Claims 1-14 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to a negative charged polymer selected from the group consisting of polysulfated glucosoglycans, glycosaminoglycans, mucopolysaccharides and mixtures thereof; and nonionic polymer selected from the group consisting of carboxymethylcellulose sodium, hydroxyethyl cellulose, hydroxypropyl cellulose and mixture thereof, wherein the molar ratio of the negatively charged polymer to the nonionic polymer is from 1:0.5 to 2. See M.P.E.P. §§ 706.03(n) and 706.03(z).

This is positively recited at page 2, lines 18-25 of the specification. There is no disclosure of other polymers which could be used. The ratio for the polymers is disclosed as being critical at page 4, lines 9-17.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

14. Claims 1-5, 8-10, 12 and 13 are rejected under 35 U.S.C.

§ 102(e) as being anticipated by Lindblad et al.

Lindblad et al. disclose a composition for use in surgical operations to prevent adhesions between tissue surfaces comprising an aqueous solution containing dextran in an amount of 7-20 % by weight and hyaluronic acid in an amount of 0.5 to 6.0 % by weight, wherein the hyaluronic acid has an average molecular weight within the range of 500,000 to 6,000,000. Lindblad et al. teach that if it is considered suitable to administer a pharmaceutical drug into the space in which the adhesions are to be prevented, this may be done by adding the drug to the adhesion preventing composition to provide a slow release of the drug (see col. 3, lines 36-43).

15. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

16. Claims 6 and 11 are rejected under 35 U.S.C. § 103 as being unpatentable over Lindblad et al.

Lindblad et al. disclose a composition for use in surgical operations to prevent adhesions between tissue surfaces comprising an aqueous solution containing dextran in an amount of 7-20 % by weight and hyaluronic acid in an amount of 0.5 to 6.0 % by weight, wherein the hyaluronic acid has an average molecular weight within the range of 500,000 to 6,000,000. The compositions may contain other physiologically preferable polysaccharides such as carboxymethylcellulose (see col. 3, lines 44-50).


17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Serial Number: 08/588,272
Art Unit: 1501

-5-

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Hulina whose telephone number is (703) 308-2974.

AH
June 23, 1996


AMY HULINA
PRIMARY EXAMINER
ART UNIT 1501